FEB 1 1 2005

K050109

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Tel: (763) 391-9533
FAX: (763) 391-9603

Preeti Jain, Director, Regulatory/Clinical Affairs

DEVICE NAME

Trillium® BioPump Plus

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

BPX80 BioPump Plus (K973011)
AFFINITY® Hollow Fiber Oxygenator with Trillium® Biopassive Surface (K973760)

DESCRIPTION OF DEVICE

The Trillium® BioPump Plus is a centrifugal blood pump which is a single use, disposable, non-pyrogenic device designed to move blood through the extracorporeal circuit by centrifugal forces created by smooth rotating cones. It is the disposable portion of the pumping system and is electromechanically coupled to the BioConsole which is the instrument that monitors and displays the flow and pressure of the blood flow. Venous blood enters the inlet port of the Bio-Pump. The smooth cones rotate in the polycarbonate housing. As the cones rotate, energy in the form of pressure and velocity is transferred from the cones to the blood. The blood is gently accelerated towards the outlet of the pump. The Bio-Pump moves the blood through the circuit at a desired pressure and flow rate by increasing or decreasing the speed of the rotating cones. This is accomplished by adjusting the BioConsole's RPM (revolutions per minute). The arterial blood is returned to the patient from the extracorporeal circuit.

STATEMENT OF INTENDED USE

The Medtronic Trillium® BioPump Plus is indicated for use only with the Medtronic Bio-Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of vena cava or aorta, liver transplants, etc.)

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The Medtronic BioPump Plus is indicated for use only with the Medtronic Bio-Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of vena cava or aorta, liver transplants, etc.)

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the BioPump Plus. The modification to the currently marketed centrifugal pump is to coat the blood contact surfaces with Trillium.

The Trillium™ BioPump Plus is being compared to the following marketed devices:

- BPX80 BioPump Plus Centrifugal Blood Pump (K973011)
- AFFINITY® Hollow Fiber Oxygenator with Trillium® Biopassive Surface (K973760)

The Trillium® BioPump Plus has the same indications statement and intended uses as the presently marketed BioPump Plus.

The Trillium® BioPump Plus has "no new technological characteristics (e.g., materials and manufacturing processes)" from the currently marketed centrifugal pumps. The technological characteristic is solely the coating material of the blood pathway:

- Trillium®

The technological characteristic of the Trillium® BioSurface is common to other medical devices (hollow fiber oxygenators) currently in commercial distribution as follows:

- AFFINITY® Hollow Fiber Oxygenator with Trillium® BioSurface (K973760)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the Trillium® BioPump Plus is substantially equivalent to other marketed extracorporeal cardiopulmonary bypass devices.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Trillium® BioPump Plus does not significantly affect safety and effectiveness and is substantially equivalent to other commercially distributed extracorporeal cardiopulmonary devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Medtronic Perfusion Systems
c/o Mr. Preeti Jain
Director, Regulatory/Clinical Affairs
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K050109
Trillium™ BioPump Plus
Regulation Number: 21 CFR 870.4370
Regulation Name: Cardiopulmonary Bypass Non-Roller type blood pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: January 14, 2005
Received: January 18, 2005

Dear Mr. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050109

Device Name: Trillium™ BioPump Plus

Indications For Use:

The Medtronic Trillium™ BioPump Plus is indicated for use only with the Medtronic Bio-Console to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of vena cava or aorta, liver transplants, etc.)

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular

510(k) Number K050109